THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

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| LOUISVILLE/JEFFERSON COUNTY METRO GOVERNMENT<br><br>Plaintiff,<br><br>v.<br><br>AMERISOURCEBERGEN DRUG CORPORATION;<br><br>CARDINAL HEALTH, INC.; and<br><br>McKESSON CORPORATION,<br><br>Defendants. | CIVIL ACTION NO. 3:17-CV-508-JHM<br><br>**COMPLAINT**<br><br>Complaint for Public Nuisance; Violations of Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961 *et seq*.; for Damages under Kentucky Revised Statutes § 446.070, and Negligence.<br><br>**JURY TRIAL DEMANDED AND ENDORSED HEREON** |

Plaintiff, LOUISVILLE/JEFFERSON COUNTY METRO GOVERNMENT ("Plaintiff" or "Louisville Metro"), brings this action against Defendants, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation (collectively, "Defendants"), for public nuisance; for violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961 *et seq.*; for damages under Kentucky Revised Statutes § 446.070, and for negligence. Plaintiff alleges that certain DEA registered distributors ***unlawfully*** sold millions of prescription opioids into Louisville/Jefferson County Metro ("Louisville Metro Area"). *See Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). Plaintiff asserts that such unlawful conduct resulted in the ***foreseeable***, widespread diversion of prescription opioids into the illicit market, 1970 U.S.C.C.A.N. §§ 4566, 4571-72, creating a serious public health and safety crisis in Louisville Metro Area involving opioid abuse, addiction, morbidity and mortality, and is a public nuisance.

Plaintiff alleges as follows:

## I. PARTIES

### A. Plaintiff.

1. Plaintiff is authorized to bring the causes of action brought herein. Plaintiff is a Kentucky Consolidated Local Government, under Kentucky Revised Statutes Chapter 67C, located in the Commonwealth of Kentucky, and as such has "all powers and privileges that cities of the first class and their counties" as well as "powers and privileges as the government may be authorized to exercise under the Constitution and general laws of the Commonwealth of Kentucky." KY. REV. STAT. ANN. § 67C.101(2). *See also* KY. REV. STAT. ANN. § 82.081 ("Each city shall constitute a corporation, with capacity to sue and be sued . . . .); KY. REV. STAT. ANN. § 83.420 ("In its corporate capacity the city may contract and be contracted with and may sue and

be sued."). Included among its powers, Plaintiff is specifically authorized to "prevent, abate, and remove nuisances." KY. REV. STAT. ANN. § 67C.101(3)(i). *Accord* KY. REV. STAT. ANN. (county fiscal court charged with "abatement of public nuisances"); KY. REV. STAT. ANN. § 67C.141 (powers of county fiscal court conferred upon consolidated local government); Louisville Metro Code of Ordinances § 96.17 ("Nothing herein shall be construed to prohibit or impair the right of the Metro Government or any of its agencies to seek abatement of public nuisances of any kind by the initiation of civil actions in the nature of injunctive relief, or otherwise.").

2. Plaintiff also has standing to bring claims under the federal RICO statute. 18 U.S.C.A. § 1961(3) ("person" includes both municipal corporations and counties); 18 U.S.C.A. § 1964 ("persons" have standing).

**B. Defendants.**

3. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, is registered with the Kentucky Secretary of State as a Delaware corporation which may be served through its registered agent for service of process, CT Corporation System, 306 West Main Street, Suite 512, Frankfort, KY 40601. AMERISOURCEBERGEN DRUG CORPORATION's principal place of business is located in Chesterbrook, Pennsylvania. AMERISOURCEBERGEN DRUG CORPORATION operates distribution centers in Kentucky, including in Louisville and, until recently, in Paducah, Kentucky.

4. Defendant, CARDINAL HEALTH, INC. is an Ohio corporation, with its principal office located in Dublin, Ohio. Under the name "Cardinal Health," Defendant performs distribution operations in Kentucky, including through a Radcliffe, Kentucky call center.[1]

[1] Cardinal Health has registered numerous of its subsidiaries for business in Kentucky, including CARDINAL HEALTH 100, Inc., CARDINAL HEALTH 108, LLC, CARDINAL HEALTH 110, LLC, CARDINAL HEALTH 113, LLC, CARDINAL HEALTH 132, LLC, CARDINAL

5. Defendant, McKESSON CORPORATION, is registered with the Kentucky Secretary of State as a Delaware corporation which may be served through its registered agent for service of process, Corporation Service Company, 421 West Main Street, Frankfort, Kentucky 40601. McKESSON CORPORATION has its principal place of business located in San Francisco, California. McKesson operates distribution centers in Kentucky, including in Louisville, Kentucky.

6. Defendants, collectively referred to herein sometimes as "Defendant Wholesale Distributors" or "Defendants," are in the chain of distribution of prescription opioids, namely hydrocodone and oxycodone. Kentucky is in the midst of a public health crisis stemming from the flood of opioids pouring into, *inter alia,* Louisville Metro Area.

7. In 1970, Congress devised a "closed" chain of distribution specifically designed to prevent the diversion of legally produced controlled substances into the illicit market. *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005); 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970). This closed-system imposes specific duties upon wholesale distributors to monitor, identify, halt and report "suspicious orders" of controlled substances. 21 C.F.R. § 1301.74; *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

8. As discussed *infra*, it has become abundantly clear that the Defendant Wholesale Distributors universally failed to comply with federal law. Plaintiff alleges the unlawful conduct

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HEALTH 200, LLC, CARDINAL HEALTH 245, CARDINAL HEALTH 248, CARDINAL HEALTH 404, LLC, and CARDINAL HEALTH 5, LLC. The registered agent for service of process for substantially all registered subsidiaries is CT Corporation System, 306 West Main Street, Suite 512, Frankfort, KY 40601.

by the Defendant Wholesale Distributors is responsible for the ***volume*** of prescription opioids plaguing our community.

9. However, the data which reveals the identity of each wrongdoer is hidden from public view in the DEA's confidential ARCOS database. *Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA[2] nor the Defendant Wholesale Distributors[3] will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

10. Consequently, Plaintiff has named *inter alia* three (3) wholesale distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) which dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into our community and that discovery will likely reveal others who

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[2] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14), attached hereto as Exhibit 1 (noting that ARCOS data is "kept confidential by the DEA").

[3] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16), attached hereto as Exhibit 2 ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

likewise engaged in unlawful conduct. Plaintiff names each of the "Big 3" herein as defendants and place the industry on notice that Plaintiff is taking action to abate the public nuisance plaguing the community. Plaintiff, to more fully identify the volume of the prescription opioids unlawfully sold into our community, will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data, including the ARCOS data.

## II. JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff's claims hinging on 21 U.S.C. § 823 and 21 C.F.R. 1301.74 necessarily raise a federal issue which is actually disputed, substantial, and capable of resolution in federal court without disrupting the federal-state balance approved by Congress. *See Gunn v. Minton*, 568 U.S. 251 (2013). This Court further has subject matter jurisdiction pursuant 28 U.S.C. § 1331 because Plaintiff's RICO claims also raise a federal question. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

12. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a), because the Plaintiff is a "citizen" of the Commonwealth of Kentucky and the named Defendants are citizens of different states, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over Defendants because they conduct business in Kentucky, purposefully direct and/or directed their actions toward Kentucky, consented to be sued in Kentucky by registering an agent for service of process, and have the requisite minimum contacts with Kentucky necessary to constitutionally permit the Court to exercise jurisdiction.

14. Venue is proper in the Western District of Kentucky pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965, as well as the District's local rules, because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a); Joint Civil Local Rules for Eastern and Western District of Kentucky, Rule 3.2.

## III. FACTUAL BACKGROUND

15. Opioid analgesics hydrocodone and oxycodone are widely diverted and improperly used, and the widespread use of these drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[4] The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[5]

16. Defendant Wholesale Distributors owe a ***duty*** under both federal law (21 U.S.C. § 823, 21 C.F.R. 1301.74) and Kentucky law (Kentucky Revised Statute § 218A.170), to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Louisville Metro Area well as those orders which Defendants knew or should have known were likely to be diverted into Louisville Metro Area.

17. The ***foreseeable*** harm from a breach of this duty is the diversion of prescription opioids for nonmedical purposes.

18. Each Defendant Wholesale Distributor repeatedly and purposefully ***breached*** its duties under state and federal law, which is a direct and proximate ***cause*** of, and/or substantial

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[4] *See* Nora D. Volkow, M.D. and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, NEW ENG. J. MED., 374;1253-63 (March 31, 2016).

[5] Special Report, FDA Commissioner Robert M. Califf, M.D., *A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED., 374;1480-85 (April 14, 2016).

factor leading to, the widespread diversion of prescription opioids for nonmedical purposes into Louisville Metro Area.

19. The unlawful diversion of prescription opioids is a direct and proximate ***cause*** of and/or substantial factor contributing to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in Kentucky and in Louisville Metro Area. This diversion and the epidemic are direct causes of harms incurred by Plaintiff itself.

20. The opioid epidemic in Kentucky, including *inter alia* in Louisville Metro Area, remains an immediate ***hazard to public health and safety***.

21. The opioid epidemic in Louisville Metro Area, is a temporary and continuous ***public nuisance*** and remains unabated.

22. Plaintiff brings this civil action against the Defendant Wholesale Distributors seeking *inter alia* ***damages*** necessary to recoup the costs incurred by Louisville Metro as a result of the nuisance, ***damages*** necessary to eliminate the hazard to public health and safety as well as ***abatement*** of the public nuisance, including an abatement fund, and a monetary award.

23. Plaintiff further brings this action to recover *inter alia* ***damages*** incurred as a result of Defendants' RICO enterprise and Defendants' negligence.

**A. Defendants Have Affirmative Duties to Maintain Effective Controls against Diversion of these Dangerous Drugs for Non-Legitimate, Non-Medical Purposes.**

24. Defendant Wholesale Distributors are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled

substances has a substantial and detrimental effect on the health and general welfare of the American people."[6]

**1. Under both federal law and Kentucky law and regulations, Defendants are required to operate a closed system to prevent the diversion of opioids for non-medical purposes.**

25. Opioids are a Schedule II controlled substance under Kentucky law. *See* 902 KY. ADMIN. REGS. 55:020. Opioids are categorized as "Schedule II" drugs because they have a "high potential for abuse" and the potential to cause "severe psychological or physiological dependence." KY. REV. STAT. ANN. § 218A.060; 21 U.S.C. § 812(b)(2)(A, C).

26. Each Defendant has an affirmative duty under federal and Kentucky law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). Kentucky's minimum requirements for wholesale drug distribution mandate that "all sales and distributions shall be in accordance with . . . the federal controlled substances laws . . . ." KY. REV. STAT. ANN. § 218A.170. Kentucky Board of Pharmacy licensure requirements mandate that a wholesale distributor "continue[] to demonstrate acceptable operational procedures, including . . . compl[iance] with all DEA regulations." 201 KY. ADMIN. REG. 2:105 §2(4)(d).

[6] *See* U.S. Department of Justice, Drug Enforcement Administration, letter to Cardinal Health dated September 27, 2006 ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.") (a copy of letter is filed at *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (filed therein in U.S. D.C. on February 20, 2012)).

27. Federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

28. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). Regardless, all flagged orders must be reported. *Id.*

29. These prescription drugs are regulated for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[7]

30. As wholesale drug distributors, each Defendant was required under Kentucky law to first be licensed by the Kentucky Cabinet for Health and Family Services. KY. REV. STAT. ANN. § 218A.150. To receive and maintain this license, each of the Defendant Wholesale Distributors assumed a duty to comply with "all applicable federal and state laws and regulations relating to controlled substances." KY. REV. STAT. ANN. § 218A.160(1)(a).

[7] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

31. Each Defendant was further required to be licensed by the Kentucky Board of Pharmacy. KY. REV. STAT. ANN. § 315.402. To receive and maintain this license, each of the Defendant Wholesale Distributors assumed a duty to "demonstrates or continues to demonstrate acceptable operational procedures, including . . . compl[iance] with all DEA regulations." 201 KY. ADMIN. REGS. 2:105 §2(4)(d).

32. Each Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each of the Defendant Wholesale Distributors is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Those requirements are adopted and incorporated into Kentucky law. KY. REV. STAT. ANN. § 218A.170(4); KY. REV. STAT. ANN. § 218A.160(1)(a); 902 KY. ADMIN. REGS. 55:010(h)(2)(b); 201 KY. ADMIN. REGS. 2:105 §2(4)(d).

33. Kentucky has declared that "[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health." KY. REV. STAT. ANN. § 218A.005(1). Further, the Kentucky legislature has declared that "effective control and regulation" of all "persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth" is necessary in order to "promote, preserve, and protect public health, safety, and welfare." KY. REV. STAT. ANN. § 315.005. Kentucky Board of Pharmacy regulations state that "[a] wholesale distributor shall not . . . operate in a manner that endangers the public health." 201 KY. ADMIN. REG. 2:105 §7.

**2. Defendants were at all relevant times on notice of their duties vis-à-vis suspicious opioid orders.**

34. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 C.F.R. 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

35. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations carefully define each participant's role and responsibilities. *See* Brief for Healthcare Distribution Management Association[8] (HDMA) and National Association of Chain Drug Stores[9] (NACDS) as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983, *22 (April 4, 2016, filed in D.C. Cir.) (hereinafter "Brief for HDMA and NACDS").

[8] The Healthcare Distribution Management Association (HDMA or HMA) is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

[9] The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart.

36. The Defendant Wholesale Distributors have admitted that they are responsible for reporting suspicious orders.[10]

37. The DEA sent a letter to each of the Defendant Wholesale Distributors on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, ***in addition*** to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[11] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[12] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[13]

38. The DEA sent a second letter to each of the Defendant Wholesale Distributors on December 27, 2007.[14] This letter reminds the Defendant Wholesale Distributors of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a

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[10] *See* Brief for HDMA and NACDS, 2016 WL 1321983, *4, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.* (regulations "in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[11] Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health (Sept. 27, 2006), at page 2 (discussing 21 U.S.C. § 823(e)) (a copy of letter is filed at *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (filed in U.S. D.C. on February 20, 2012)).

[12] *Id.,* at page 1.

[13] *Id.,* at page 2.

[14] *See* Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health (Dec. 27, 2007) (a copy of letter is filed at *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-8 (filed in U.S. D.C. on February 20, 2012)).

system to disclose to the registrant suspicious orders of controlled substances."[15] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
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> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
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> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
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> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating

[15] *Id.*

> "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
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> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[16]

Finally, the DEA letter references the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007) [2007 WL 1886484], which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[17]

39. Defendant Wholesale Distributors "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[18]

40. Defendant Wholesale Distributors knew they were required to monitor, detect, report, and refuse to fill suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise

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[16] *Id.*

[17] *Id.*

[18] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, 2012 WL 1637016, *2 (C.A. D.C.) (May 9, 2012).

characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

**3. At all relevant times, each Defendant was acting under a duty to guard against the diversion of prescription opioids for non-medical purposes.**

41. Each of the Defendant Wholesale Distributors sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Louisville Metro Area and/or to retailers from which Defendants knew drugs were likely to be delivered and/or diverted into Louisville Metro Area.

42. Defendant Wholesale Distributors owe a duty to maintain effective controls to prevent diversion in Louisville Metro Area, including a duty to monitor, detect, report, and refuse to fill suspicious orders of prescription opioids originating from Louisville Metro Area and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area.

43. Defendant Wholesale Distributors owe a duty to detect suspicious orders of prescription opioids originating from Louisville Metro Area and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area.

44. Defendant Wholesale Distributors owe a duty to investigate suspicious orders of prescription opioids originating from Louisville Metro Area and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area. *See Masters Pharmaceuticals, Inc.; Decision and Order*, 80 FR 55418-01, 55477 (September 15, 2015).

45. Defendant Wholesale Distributors owe a duty to refuse suspicious orders of prescription opioids originating from Louisville Metro Area and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area.

46. Defendant Wholesale Distributors owe a duty to report suspicious orders of prescription opioids originating from Louisville Metro Area and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area.

47. Defendant Wholesale Distributors owe a duty to maintain effective controls against the diversion of prescription opioids into illicit markets in Louisville Metro Area.

48. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

49. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Louisville Metro Area, and the damages caused thereby.

**B. Deliberately, Knowingly, and for Profit, Defendants Breached Their Duties.**

**1. Defendant Wholesale Distributors' Compliance with their legal duties is critical, particularly considering the sharp increase in, and large numbers of, opioid prescriptions.**

50. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain

effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[19]

51. The United States consumes opioid pain relievers at a greater rate than any other nation.

52. The sheer volume of prescription opioids distributed to pharmacies in Louisville Metro Area is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. *Masters Pharmaceuticals, Inc.; Decision and Order*, 80 FR 55418-01, 55482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a/CVS/Pharmacy Nos. 219 and 5195*, 77 FR 62,316, 62,322 (2012)); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

**2. Defendants breached their duties.**

53. Plaintiff is of the information and belief that the Defendant Wholesale Distributors failed to report to the DEA "suspicious orders" originating from Louisville Metro Area and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area.

54. Plaintiff alleges that the Defendant Wholesale Distributors unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Louisville Metro Area and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area.

[19] *See* Declaration of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶10, *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (filed in U.S. D.C. on February 20, 2012).

55. Kentucky Revised Statutes Chapter 218A, including §§ 218A.160, 218A.170(4); Kentucky Administrative Regulations, Title 902, Chapter 55; 21 U.S.C. §§ 812, 823; 21 C.F.R. § 1301.74; 28 C.F.R. § 0.100, and laws and regulations incorporated therein, are public safety laws.

56. The Kentucky Legislature's intent in promulgating the Kentucky Controlled Substances Act, was to promote the "preservation of public safety and public health." KY. REV. STAT. ANN. §218A.005(1).

57. Each Defendant Wholesale Distributor breached its duty to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels.

58. Each Defendant Wholesale Distributor breached its duty to design and operate a system to disclose suspicious orders of controlled substances and failed to inform the DEA of "suspicious orders for drugs when discovered" in violation of 21 C.F.R. § 1301.74(b) and Kentucky laws and regulations incorporating federal requirements. KY. REV. STAT. ANN. § 218A.170(4); KY. REV. STAT. ANN. § 218A.160(1)(a); 902 KY. ADMIN. REGS. 55:010(h)(2)(b).

59. Each Defendant Wholesale Distributor breached its duty to provide effective controls and procedures to guard against theft and diversion of controlled substances in violation of Kentucky regulations and federal law. *See, e.g.*, 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b); KY. REV. STAT. ANN. § 218A.170(4); KY. REV. STAT. ANN. § 218A.160(1)(a); 902 KY. ADMIN. REGS. 55:010(h)(2)(b).

60. Defendant Wholesale Distributors' violations of public safety statutes constitute prima facie evidence of negligence under Kentucky law.

61. Defendant Wholesale Distributors breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels. *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

62. Defendant Wholesale Distributors breached their duty to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Louisville Metro Area and/or which Defendants knew or should have known were likely to be delivered and/or diverted into Louisville Metro Area.

**3. Defendants' serial violations of the law.**

63. As a result of the decade-long refusal by the Defendant Wholesale Distributors to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[20] These actions include the following:

(a) On April 24, 2007, the DEA issued *an Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

[20] *The Drug Enforcement Administration's Adjudication of Registrant Actions*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014).

(b) On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

(c) On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

(d) On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

(e) On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

(f) On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

(g) On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado;

(h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;

(j) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

(k) On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a

> $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

64. Rather, than abide by their non-delegable duties under public safety statutes, the Defendant Wholesale Distributors, individually and collectively through trade groups in the industry, pressured the U.S. Dept. of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[21]

65. Meanwhile, the opioid epidemic rages unabated in Louisville Metro Area.

**4. Defendants knowingly breached their mandatory duties.**

66. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the Defendant Wholesale Distributors. They pay fines as a cost of doing business in an industry which generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. And, as bluntly noted by Cardinal Health in its filings in *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012), "suspension … will not address the harm DEA

[21] See Lenny Bernstein and Scott Higham, Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control, THE WASHINGTON POST (October 22, 2016); Lenny Bernstein and Scott Higham, Investigation: U.S. senator calls for investigation of DEA enforcement slowdown amid opioid crisis, THE WASHINGTON POST (March 6, 2017); *Eric Eyre, DEA agent: 'We had no leadership' in WV amid flood of pain pills*, Charleston Gazette (February 18, 2017).

alleges because it will not prevent pharmacies filling illegitimate prescriptions from simply obtaining controlled substances from another distributor."[22]

67. The Defendant Wholesale Distributors' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities, demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

68. The unlawful conduct by the Defendant Wholesale Distributors is purposeful and intentional. Bluntly, they refuse to abide by the duties imposed by law which are required to maintain a Kentucky license to distribute prescription opioids and to maintain their DEA registration. Defendants acted with actual malice, *i.e.*, Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm. Defendants acted willfully. Defendants acted with such gross negligence as to indicate a wanton disregard of the rights of others. Punitive damages are necessary to deter similar conduct in the future.

69. Defendant Wholesale Distributors have publicly disavowed any duty beyond *reporting* suspicious orders and, even then, have claimed they were not required to report all suspicious orders. In *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (D.C. Cir. April 4, 2016), the Healthcare Distribution Management Association and National Association of Chain Drug Stores submitted amicus briefs regarding the legal duty of

[22] Memorandum of Points of Authorities in Support of Cardinal Health's Motion for Temporary Restraining Order (Doc. 3-1), at p. 22, *Cardinal Health, Inc. v. Holder,* No. 1:12-cv-00185-RBW (D.C. Cir. Feb. 3, 2012).

wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued that**:**

- The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled." (emphasis in original) (Brief for HDMA and NACDS, 2016 WL 1321983, at ** 4-5);

- The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications." (internal citations & quotes omitted) (emphasis in original) (*Id*., at *8);

- The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious." (*Id*., at *14);

- The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties." (*Id*., at *22);

- The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." (emphasis in original) (*Id*., at **24-25); and,

- Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors - which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands." (*Id*., at *26).

70. The positions taken by the trade groups is emblematic of the position taken by the Defendant Wholesale Distributors in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[23]

71. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have a duty to report all suspicious orders and also has duties beyond reporting. *Masters Pharmaceutical, Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The Circuit Court upheld the revocation of Masters Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors "must . . . decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." 861 F.3d at 212-13. Masters Pharmaceutical was in violation of legal requirements not only because it failed to report suspicious orders, but also because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 217-19, 222-23. Before a distributor may ship a suspicious order, a distributor's investigation must dispel all red flags giving rise to suspicious circumstance. *Id*. at 222-23. The Circuit Court also rejected the argument made by the Healthcare Distribution Management Association and National Association of Chain Drug Stores, that, allegedly, the DEA had created or imposed new duties. *Id*. at 221-22.

72. Wholesale Distributor McKesson has specifically admitted to breaching its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January

[23] *See* Amicus Curiae Brief of HDMA, *Cardinal Health, Inc. v. United States Dept. Justice*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road" because they claim (inaccurately) that the "DEA has not adequately explained them.").

2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5)."[24] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[25] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq.," at numerous nationwide McKesson Distribution Centers."[26]

73. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[27] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor

[24] *See* Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and McKesson Corporation, effective date January 17, 2017.

[25] *Id.* at 4.

[26] *Id.* at 3.

[27] *Id.* at 4.

its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[28] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 130l.74(b)."[29] The 2017 Memorandum of Agreement and the associated Settlement Agreement and Release revealed to the public that McKesson was not complying with the 2008 Settlement Agreement. As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[30]

### C. The Opioid Plague in Louisville Metro Area, Was Caused by, and Is the Proximate Result of, Defendants' Breaches of Mandatory Duties to Maintain Effective Controls to Prevent the Diversion of Dangerous, Highly Addictive Opioids.

74. Defendant Wholesale Distributors' failure to monitor, detect, investigate, refuse to fill, and report suspicious orders is a direct and proximate ***cause*** of, and/or substantial factor contributing to, the diversion of millions of doses of prescription opioids into the illicit market for purposes other than legitimate medical use in Louisville Metro Area.

75. The unlawful conduct by Defendant Wholesale Distributors ***caused*** the very harm the federal and Kentucky statutes and regulations were intended to prevent; namely, the diversion of prescription opioids for illegitimate and/or nonmedical purposes.

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[28] *Id.*

[29] *Id.* at 4. *See also* Settlement Agreement and Release between the United State of America (acting through the Department of Justice and on behalf of the Drug Enforcement Administration) and McKesson Corporation, effective date January 17, 2017 ("2017 Settlement Agreement and Release") ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.").

[30] *See* 2017 Settlement Agreement and Release at p. 6.

76. The unlawful diversion of prescription opioids is a direct and proximate ***cause*** of and/or a substantial factor leading to prescription opioid abuse, addiction, morbidity and mortality in Louisville Metro Area.

77. The unlawful diversion of prescription opioids is a direct and proximate ***cause*** of and/or a substantial factor leading to the prescription opioid epidemic currently plaguing Louisville Metro.

78. The unlawful diversion of prescription opioids is a direct and proximate ***cause*** of and/or a substantial factor leading to the heroin epidemic currently plaguing Louisville Metro.

79. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions**.**[31]

80. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[32]

81. The increased use of prescription painkillers for reasons other than legitimate medical use (for the high they cause), along with growing sales, has contributed to a large number of overdoses and deaths.[33]

82. There is "a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[34]

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[31] *See* Nora D. Volkow, M.D. and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain–Misconceptions and Mitigation Strategies*, NEW ENG. J. MED., 374;1253-63 (March 31, 2016).

[32] *See* Special Report, FDA Commissioner Robert M. Califf, M.D., *et al., A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED., 374;1480-85 (April 14, 2016).

[33] *See* Press Release, *Prescription painkiller overdoses at epidemic levels*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (November 1, 2011).

83. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioids are forty times more likely to be addicted to heroin.[35]

84. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[36] The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,*** specifically among persons who report past-year dependence or abuse.

**D. Defendants' Misrepresentations and Fraudulent Intent.**

85. Defendants' intent to violate the law and engage in an enterprise to drive up their profits from and sales of diverted opioids is evident from: (1) Defendants' repeated violations of the law, including notices of violations and settlements; (2) Defendants' failures to adequately implement stated anti-diversion policies; (3) Defendants' failures to adequately fund anti-diversion efforts; and (4) Defendants' continued and ongoing maintenance of a corporate

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[34] *See* Richard C. Dart, M.D., Ph.D., et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J. MED., 372;241-248, 245 (January 15, 2015).

[35] *See* CDC Vital Signs Fact Sheet, *Today's Heroin Epidemic*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (July 2015).

[36] *See* Wilson M. Compton, M.D., M.P.E., et al., *Relationship between Nonmedical Prescription Opioid Use and Heroin Use*, NEW ENG. J. MED., 374;154-63 (January 14, 2016).

structure that rewards increases in opioid sales and encourages the distributors' employees/agents to turn a blind eye to suspicious conduct.

86. To protect their registered distributor status with the Kentucky Cabinet for Health and Family Services and the DEA, so that they can continue to generate profits, the Defendant Wholesale Distributors undertook efforts to fraudulently assure the public that they were in fact complying with their legal obligations. Through such statements, the Distributors attempted to assure the public they are working to curb the opioid epidemic.

87. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[37] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or Cardinal Health had such a system, but it ignored the results.

88. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[38] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

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[37] Lenny Bernstein *et al*., How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job', THE WASHINGTON POST, October 22, 2016, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.744e85035bdc (last visited July 12, 2017).

[38] Scott Higham *et al*., Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse, THE WASHINGTON POST, December 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.68a58d17478e (last visited July 12, 2017).

89. Moreover, through their participation in the Healthcare Distribution Management Association ("HDMA"), the trade association of pharmaceutical distributors, the Distributors admit that they are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[39] The Distributors state the HDMA Guidelines "were prepared in recognition of the growing problem of misuse and diversion of Controlled Substances (CS) and the critical role of each member of the supply chain in helping to enhance security."[40] Given Defendants' ability to know where opioids are being sent and how order volumes change year after year, they are well aware of their unique ability to identify suspicious sales volumes and patterns, but nonetheless chose not to report suspicious orders or take any actions to refuse to fill suspicious orders.

### E. Louisville Metro and the Public Welfare Have Been Damaged by Defendants' Participation in the Unlawful Diversion of Dangerous, Highly Addictive Opioids.

#### 1. Opioid-related addiction and death has reached epidemic proportions.

90. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[41]

91. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2014 there were almost 19,000 overdose deaths in the United States associated with prescription opioids.[42]

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[39] *See* Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (dated in or around 2012) ("HDMA Guidelines").

[40] *Id.*

[41] *See* Robert M. Califf, M.D., et al., *A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED., 374;1480 (April 14, 2016).

92. Barack Obama, then President of the United States, declared a prescription opioid and heroin epidemic.[43]

93. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[44]

94. Fundamentally, prescription opioids and heroin are elements of a larger epidemic of opioid-related disorders and death. Viewing them from a unified perspective is essential to improving public health.[45]

**2. While the opioid epidemic is a national tragedy, the statistics are particularly tragic in Kentucky and Louisville Metro.**

95. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an opioid.[46]

96. From 2000 to 2015 more than half a million people died from drug overdoses. 91 Americans die every day from an opioid overdose.[47]

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[42] *Id.*

[43] *See* Barack Obama, President of the United States, Proclamation 9499, *Prescription Opioid and Heroin Epidemic Awareness Week*, 2016, 81 FR 65173 (September 16, 2016).

[44] *See* Rose A. Rudd, MSPH, et al., *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention, 65(50-51);1445–1452 (December 30, 2016).

[45] *See* Wilson M. Compton, M.D., M.P.E., et al., *Relationship between Nonmedical Prescription Opioid Use and Heroin Use*, NEW ENGL. J. MED., 374;154 (Jan. 14, 2016).

[46] Understanding the Epidemic, Drug overdose deaths in the United States continue to increase in 2015, Centers for Disease Control and Prevention, available at https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Aug. 8, 2017).

[47] *Id.*

97. Overdoses from prescription opioids are a driving factor in the increase in opioid overdose deaths. Kentucky has been devastated by the opioid epidemic. In Kentucky, more people died from an opioid drug overdose in from 2012-2016 than from motor vehicle accidents. Jefferson County, Kentucky reported 364 overdose deaths last year, by far the most in the state and up from 268 in 2015.[48]

98. Kentucky is one of the States identified by the United States Center for Disease Control and Prevention (CDC) as having a statistically significant drug overdose death rate increase from 2014 to 2015.[49] The percent increase from 2014 to 2015 was 21%.

99. And yet, opioids continue to be distributed and dispensed in Kentucky at an alarming rate. **From 2012 through the middle of 2017, more than 197 million doses of prescription opioids, including hydrocodone, oxycodone, tramadol, and oxymorphone, were dispensed in Jefferson County, Kentucky which has a population of approximately 760,000 people**. **That is more than 258 doses of prescription opioids for every man, woman, and child in Jefferson County, Kentucky.** During this same time period, more than 3,500,000 doses of overdose antidotes, including naloxone, have been dispensed in Jefferson County, Kentucky – nearly 5 per person.[50]

100. The tragic opioid epidemic impacts infants. The use of opiates during pregnancy can result in a drug withdrawal syndrome in newborns called Neonatal Abstinence Syndrome

[48] Commonwealth of Kentucky, Justice & Public Safety Cabinet, Kentucky Office of Drug Policy 2016 Overdose Fatality Report, available at https://odcp.ky.gov/Reports/2016%20ODCP%20_Overdose%20Fatality%20Report%20Final.pdf (last visited Aug. 17, 2017).

[49] Drug Overdose Death Data, CDC, available at https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited Aug. 8, 2017).

[50] *See* KASPER Quarterly Trend Reports, available at http://www.chfs.ky.gov/os/oig/kaspertrendreports (last visited Aug. 17, 2017).

(NAS). There was a five-fold increase in the proportion of babies born with NAS from 2000 to 2012, when an estimated 21,732 infants were born with NAS —equivalent to one baby suffering from opiate withdrawal born every 25 minutes.[51] The cost of treating these infants is significant. Newborns with NAS were more likely than other babies to also have low birthweight and respiratory complications. In 2012, newborns with NAS stayed in the hospital an average of 16.9 days (compared to 2.1. days for other newborns).[52]

101. The opioid epidemic has placed increased budgetary costs upon Louisville Metro related to its health services and expenditures, criminal law enforcement expenses, and other expenditures related to the opioid crises.

102. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Louisville Metro.

103. Prescription opioid abuse, addiction, morbidity, and mortality are a temporary public nuisance in Louisville Metro, which remains unabated.

104. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Louisville Metro.

105. Heroin abuse, addiction, morbidity, and mortality are a temporary and continuing public nuisance in Louisville Metro, which remains unabated.

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[51] Dramatic Increases in maternal Opioid Use and Neonatal Abstinence Syndrome, NIH National Institute on Drug Abuse, available at https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (last visited Aug. 8, 2017).

[52] *Id.*

106. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[53]

107. "A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain."[54]

**3. General declaration of damages applicable to all Counts herein.**

108. The unlawful conduct by the Defendant Wholesale Distributors has created hazards to public health and safety and a temporary and continuing public nuisance in Louisville Metro Area, which remains unabated.

109. Plaintiff seeks economic damages from the Defendant Wholesale Distributors as reimbursement for the costs association with past efforts to eliminate the hazards to public health and safety.

110. Plaintiff seeks economic damages from the Defendant Wholesale Distributors to pay for the damages incurred and the future costs required to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

111. Plaintiff seeks to hold the Defendant Wholesale Distributors financially responsible for the economic costs of eliminating the hazards to public health and safety and abating the temporary public nuisance caused by the unlawful conduct recited herein.

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[53] *See* Rose A. Rudd, MSPH, et al, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention, 65(50-51);1445–1452 (December 30, 2016).

[54] *See* Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015, available at http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-injury-research-and-policy/publications-resources/CenterPubs/2015-prescription-opioid-epidemic-report.pdf (last visited Aug. 10, 2017).

112. Plaintiff seeks punitive damages to deter the Defendant Wholesale Distributors and others from committing like offenses in the future. Defendants acted with actual malice, willfully, and with such gross negligence as to indicate a wanton disregard for the rights of others, and said actions have a great probability of causing substantial harm.

**F. Tolling of the Statute of Limitations and Estoppel**

113. Plaintiff contends that the harm caused by the unlawful actions of the Defendant Wholesale Distributors continues.

114. The continued tortious conduct by the Defendant Wholesale Distributors causes a repeated or continuous injury. The damages have not occurred all at once but have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing has not ceased. The public nuisance remains unabated.

115. Plaintiff's claims are subject to both equitable estoppel, stemming from Defendant Wholesale Distributors' knowingly and fraudulently concealing the facts alleged herein, and equitable tolling, stemming from Defendants' wrongful concealment and from Plaintiff's inability to obtain vital information underlying its claims.

**1. Defendants Deliberately Concealed Their Misconduct and Misrepresented their Compliance with their Legal Obligations.**

116. Defendants are estopped from relying upon a statute of limitations defense because the Distributors undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public that they were undertaking efforts to comply with their obligations under the CSA. Separate and apart from Defendants' acts of concealment, any applicable statutes of limitation are properly tolled because Plaintiff did not know and could not have learned the true facts underlying their claims until shortly before filing its Complaint.

117. Indeed, Defendant Wholesale Distributors are estopped by their own fraudulent concealment from asserting the statute of limitations as an affirmative defense against Plaintiff's claims.

118. Defendants misrepresented their compliance with the law and prevented discovery by the public and by the Plaintiff of their wrongful actions.

119. Notwithstanding the allegations set forth above, the Defendant Wholesale Distributors affirmatively assured the public they are working to curb the opioid epidemic.

120. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[55] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or Cardinal Health had such a system, but it ignored the results.

121. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[56] It was only in January 2017 that the agreement accompanying the $150,000,000 fine against McKesson revealed that McKesson

[55] Lenny Bernstein, et al., How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job', THE WASHINGTON POST, October 22, 2016, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.744e85035bdc (last visited June 16, 2017).

[56] Scott Higham, et al., Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse, THE WASHINGTON POST, December 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.68a58d17478e (last visited June 16, 2017).

was, yet again, violating its legal obligations to maintain effective controls against diversion, including through monitoring, reporting and preventing distribution of suspicious orders.

122. Additionally, even though the Defendant Wholesale Distributors entered into settlements and consent orders, outside of certain limited admissions made in those recently publicized documents, Defendants have not admitted liability or any wrongdoing. On the contrary, in connection with these settlements, the Defendant Wholesale Distributors have repeatedly contended they were in compliance with the law.

123. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendant Wholesale Distributors, through their trade associations, Healthcare Distribution Management Association (HDMA) and National Association of Chain Drug Stores (NACDS), filed an *Amicus* brief in *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Administration*, Case No. 15-1335; 2016 WL 1321983 (D.C. Cir. Apr. 4, 2016), which made the following statements:

- "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
- "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."
- "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."
- "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

Through the above statements made on their behalf by their trade associations, the Defendant Wholesale Distributors not only acknowledged that they understood their obligations under the law, but they further affirmatively represented that their conduct was in compliance with those obligations.

124. In light of their statements to the media, in legal filings, and in settlements, it is clear that Defendant Wholesale Distributors had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

125. Louisville Metro has diligently sought to discover and prevent the causes of the opioid-based public nuisance in Louisville Metro Area.

126. Defendants' actions were affirmatively designed to prevent, and did prevent, discovery of Louisville Metro's cause of action. Defendants' actions constituted actual artifice to prevent knowledge of the facts. Defendants committed affirmative acts of concealment and misrepresentation to exclude suspicion and prevent inquiry.

127. Plaintiff reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

128. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

129. Defendants continually and secretly engaged in their scheme to avoid compliance with their reporting obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful failure to report suspicious sales because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiff was unable to

obtain vital information bearing on their claims absent any fault or lack of diligence on Plaintiff's part.

**2. Defendant Wholesale Distributors' Conduct Is Exposed.**

130. On December 17, 2016, the Charleston Gazette-Mail published a groundbreaking, Pulitzer Prize-Winning story.[57]

131. The journalist had been seeking drug shipping sales data since August 8, 2016, when the Charleston Gazette-Mail Newspaper sought access to certain limited ARCOS data. However, "[t]he wholesalers and their lawyers fought to keep the sales numbers secret in previous court actions brought by the newspaper."[58] But, finally, "[t]he Gazette-Mail obtained previously confidential drug shipping sales records, . . . [which] disclose the number of pills sold to every pharmacy in the state."[59]

132. With the data in its possession, on December 17, 2016, the Gazette-Mail published its shocking analysis of the data.[60] The Gazette-Mail made the following statements, based on the limited West Virginia ARCOS data in its possession about the Defendants conduct in West Virginia:

[57] Eric Eyre of *Charleston Gazette-Mail*, Charleston, WV, The 2017 Pulitzer Prize Winner in Investigative Reporting, available at http://www.pulitzer.org/winners/eric-eyre (last visited July 3, 2017).

[58] Eric Eyre, Drug firms poured 780M painkillers into WV amid rise of overdoses, Charleston Gazette-Mail, December 17, 2016, available at http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses (last visited July 3, 2017).

[59] *Id*.

[60] *Id*.

- "In six years, drug wholesalers showered the state with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two painkillers."[61]

- "While the death toll climbed, drug wholesalers continued to ship massive quantities of pain pills."[62]

- The quantity of opioids delivered during this period "amount to 433 pain pills for every man, woman and child in West Virginia."[63]

- "The nation's three largest prescription drug wholesalers — McKesson Corp., Cardinal Health and AmerisourceBergen Drug Co. — supplied more than half of all pain pills statewide."[64]

- "For more than a decade, the same distributors disregarded rules to report suspicious orders for controlled substances in West Virginia to the state Board of Pharmacy, the Gazette-Mail found."[65]

- "Year after year, the drug companies also shipped pain pills in increasing stronger formulations, DEA data shows."[66]

133. Given the Defendant Wholesale Distributors' efforts to mislead the public and conceal its unlawful conduct, as alleged above, Plaintiff did not have any reason to know of the Defendant Wholesale Distributors' unlawful conduct or their role in creating the opioid nuisance.

134. Plaintiff was relieved of any duty to investigate because it reasonably and justifiably relied on Defendants to fulfill their reporting requirements and comply with the law. Plaintiff did not discover and could not have discovered, despite all due diligence, the schemes

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Id.*

alleged herein. The conduct revealed in December 2016 and January 2017 concerned only West Virginia counties (with regard to the Charleston Gazette-Mail publication) or a single distributor (with regard to the DOJ fine against McKesson).

135. Plaintiff's claims were equitably tolled until Plaintiff discovered Defendants' conduct shortly before the filing of the Complaint. Defendants are further equitably estopped by their own actions, including their fraudulent concealment, from asserting statute of limitations defenses to Plaintiff's claims.

## IV. CAUSES OF ACTION

### COUNT I
### PUBLIC NUISANCE
### KENTUCKY COMMON LAW

136. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further allege as follows.

137. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of and/or a substantial factor leading to Plaintiff's injury. *See* Restatement Second, Torts § 821B.

138. Kentucky has declared that "[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health." KY. REV. STAT. ANN. § 218A.005(1). Further, the Kentucky legislature has declared that "effective control and regulation" of all "persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth" is necessary in order to "promote, preserve, and protect public health, safety, and welfare." KY. REV. STAT. ANN. § 315.005. Kentucky Board of Pharmacy regulations state that "[a] wholesale

distributor shall not . . . operate in a manner that endangers the public health." 201 KY. ADMIN. REG. 2:105 §7.

139. By causing dangerously addictive drugs to flood the community, and to be diverted for illicit purposes, in contravention of federal and Kentucky law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of Louisville Metro Area to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' diversion of dangerous drugs has caused substantial annoyance, inconvenience, and injury to the public.

140. By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a course of conduct that injuriously affects the safety, health, and morals of the people of Louisville Metro Area.

141. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of Louisville Metro Area.

142. The residents of Louisville Metro Area have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property. Specifically, widespread distribution of prescription opioids for illicit purposes jeopardizes these common rights, and the illegal widespread distribution of prescription opioids would not be possible but for the unlawful and intentional acts, or failures to act, by Defendants.

143. Defendants intentionally, unlawfully, and recklessly distribute and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing

widespread distribution of prescription opioids in and/or to Louisville Metro Area illegally, resulting in addiction and abuse, an elevated level of crime, death and injuries to Louisville Metro Area residents, a higher level of fear, discomfort and inconvenience to the residents of Louisville Metro Area, and direct costs to Plaintiff itself.

144. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure Plaintiff.

145. Defendants have unlawfully and/or intentionally distributed opioids without maintaining effective controls against diversion. Such conduct was illegal. Defendants violated the federal and Kentucky Controlled Substances Acts. Defendants' failures to maintain effective controls against diversion include Defendants' failures to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

146. Defendants have caused a substantial and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property. The Defendants' conduct is proscribed by state and federal law. Here, Defendants are not in compliance with applicable law or are otherwise negligent in carrying out their respective enterprises.

147. Defendants' conduct in illegally distributing and selling prescription opioids where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally in Louisville Metro Area is of a continuing nature and has produced a significant effect upon the public's rights, including the public's right to health and safety.

148. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

149. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Louisville Metro Area will be diverted, leading to abuse, addiction, crime, and public health costs.

150. As a result of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance to person and property.

151. Defendants know, and/or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

152. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

153. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Louisville Metro Area. Defendants are in the business of distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal and Kentucky law. *See, e.g.*, 21 U.S.C.A. § 812 (b)(2); KY. REV. STAT. ANN. § 218A.060.

154. Defendants' conduct in marketing, distributing, and selling prescription opioids which the Defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to Louisville Metro Area residents and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

155. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to Louisville Metro Area residents, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

156. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Louisville Metro Area not only causes deaths and injuries, but also creates a palpable climate of fear among Louisville Metro Area residents where opioid diversion, abuse, and addiction are prevalent and where they tend to be used frequently.

157. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

158. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' unique position within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

159. The presence of diverted prescription opioids in Louisville Metro Area, and the consequence of prescription opioids having been diverted in Louisville Metro Area, proximately results in significant costs to Plaintiff in order to enforce the law, equip its police force, respond to emergencies, and treat the victims of opioid abuse and addiction.

160. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Louisville Metro Area a safer place to live.

161. Defendants' conduct is a direct and proximate cause of and/or a substantial factor leading to deaths and injuries to Louisville Metro Area residents, costs borne by Plaintiff, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

162. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of Louisville Metro Area's residents, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

163. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Louisville Metro Area, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids without reporting, and without refusing to fill, suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids. Such actions were inherently dangerous.

164. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids without maintaining effective controls against diversion, including monitoring, reporting, and

refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Louisville Metro Area.

165. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

166. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm. Defendants acted willfully, and with such gross negligence as to indicate a wanton disregard of the rights of others.

167. As a direct and proximate result of Defendants' conduct, which was a substantial factor creating the harms alleged herein, Louisville Metro Area has suffered actual injury and damages including, but not limited to, significant increased expenses for police, emergency, ambulance services, health, prosecution, corrections and other services. While Plaintiff normally has some expenses related to these services, the expenses have been significantly increased as a direct and proximate result of Defendants' conduct, which was a substantial contributing factor, and thus constitute specific and special injuries. The increased expenditures have been a necessary means to respond to issues created by unlawful opioid prescription drugs in Louisville Metro Area, but much greater expenditures are needed to abate the serious problems caused by the opioid epidemic.

168. Plaintiff has sustained specific and special injuries because its damages include, *inter alia,* health services and law enforcement expenditures, and include without limitation costs sustained by first responders, costs sustained by the government medical examiners and crime labs, Health and Human Services costs, costs sustained by the Plaintiff's payments for health

services, including *inter alia* hospital and ambulance operations, costs related to opioid addiction treatment and overdose prevention, and payments by governmental payor programs, such as employee health insurance. Thus, Plaintiff seeks recovery for its own harm.

169. Plaintiff further seeks to abate in the future this nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent interference with a right common to the public. Such abatement is feasible here and can be accomplished by providing financial resources to Plaintiff to combat the problems arising from unlawfully diverted opioids.

170. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of prescription opioid abuse and heroin use resulting from Defendants' abdication of their gate-keeping duties has caused harm to the entire community that includes, but is not limited to:

a. The high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Nor have children escaped the opioid epidemic unscathed. Easy access to prescription opioids has made opioids a recreational drug of choice among Kentucky teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those Louisville Metro Area residents who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages,

or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids, further impacting the public right to health and safety.

d. The opioid epidemic has increased health care costs.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' failure to maintain effective controls against diversion of dangerously addictive prescription opioids for non-medical use and abuses has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. Increased supply, due to Defendants' conduct, led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has increased the demands on health care services and law enforcement in Louisville Metro Area.

i. The categories of damages sustained by Plaintiff include, among others, opioid-related costs and burdens placed upon first responders, whose resources and expertise are necessary to keep our community safe. The resources of *inter alia* emergency responders, police, medical, and ambulance services have been drained, over and above typical municipal community needs, as a result of the opioid epidemic in this County.

j. The significant unreasonable interference with the public rights caused by Defendants' conduct has taxed the human, medical, public health, law enforcement, and financial resources of Plaintiff.

k. Defendants' interference with the comfortable enjoyment of life in Louisville Metro Area is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

**COUNT II**
**RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO)**
**18 U.S.C. §§ 1961, *et seq.***

171. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further allege as follows.

172. Each Defendant is associated with an enterprise which affects interstate commerce for purposes which include the illegal distribution of opioids. As explained herein, each Defendant Wholesale Distributor conducted or participated in the enterprise's affairs through commission of criminal offenses which constitute a pattern of racketeering activity.

173. Defendant corporations are "persons" within the meaning of 18 U.S.C. § 1961(3) which conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962.

174. Plaintiff was injured in its business or property as a result of each Defendant's wrongful conduct and is a "person" who can bring an action for violation of section 1962, as that term is defined in 18 U.S.C. § 1961(3). "Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee...." 18 U.S.C. § 1964.

**A. The Opioids Diversion Enterprise.**

175. Each Defendant formed an association-in-fact enterprise ("Opioids Diversion Enterprise"), and participated in the affairs of this enterprise when distributing highly dangerous, addictive opioid drugs in Louisville Metro Area. Each Defendant's Opioids Diversion Enterprise consists of (a) each Defendant, including its employees, co-Defendant subsidiaries, and agents; and (b) each Defendant's retail pharmacies which placed orders for vast quantities of opioids. Indeed, the Defendants could not have diverted opioids without the participation of retail pharmacies. The events described herein required retail pharmacies to place orders for these vast quantities of opioids.

176. Each Defendant and its respective pharmacy customers participated in the conduct of the Opioids Diversion Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity, which includes multiple violations of the Kentucky Controlled Substances Act, constituting a felony, and multiple instances of federal mail and wire fraud.

177. Each Defendant's Opioids Diversion Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to profit from the sale of opioid prescription pills. Each Defendant conducted this enterprise notwithstanding that its failure to abide by mandatory checks and balances constituted unlawful diversion of a dangerous controlled substance.

178. The system is structured such that wholesalers and pharmacies see greater profits at higher volumes. As a result, these companies are financially discouraged from undertaking efforts to combat opioid abuse. Wholesale Distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost ("WAC"). Discounts and rebates may be offered by the manufacturers based on, *inter alia*, market share and volume.

Thus, the Defendant Wholesale Distributors are incentivized to order greater amounts so that they can decrease the cost per pill. The Defendant Wholesale Distributors used the decreased cost per pill to increase their market share (and thus, profits), by offering more competitive prices, or they maintained their prices and pocketed the difference as additional profit. Either way, increased sales volumes result in increased profits. At every turn, each Defendant maximized its profits through discounts and rebates by ordering and selling more opioids.[67]

179. As described above and expressly incorporated herein, the Defendant Wholesale Distributors: (a) were placed on notice by the DEA, and were the subject of repeated DEA enforcement actions; and (b) misrepresented their compliance with their legal obligations to maintain a closed system.

180. Each Defendant's Opioid Diversion Enterprise has caused opioids to be abused throughout Louisville Metro Area, with an ongoing cascade of human suffering and death that continues to consume the resources of Plaintiff's health and human services, health care, and law enforcement systems.

181. Each Defendant and its respective retail pharmacy customers were willing participants in the Opioids Diversion Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

**B. Conduct of the Opioids Diversion Enterprise**

182. To accomplish the common purpose of profiting from the sale of opioid prescription pills, each Defendant's Opioids Diversion Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general

[67] "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," The Kaiser Family Foundation, March 2005.

public, Plaintiff, Kentucky consumers, the Kentucky Board of Pharmacy, and the Kentucky Cabinet for Health and Family Services, that it was fulfilling the requirements of its Kentucky wholesale distributor license when, in fact, the duty to maintain effective controls to prevent diversion for non-medical purposes was being ignored in pursuit of ever increasing profits.

183. The persons engaged in each Defendant's Opioids Diversion Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities. Typically, this communication occurred, and continues to occur, through the use of the wires and mail in which each Defendant and its respective retail pharmacy customers communicate to facilitate the prescription opioid orders.

184. Each Defendant's Opioids Diversion Enterprise functions as a continuing unit for the purposes of profiting from the sale of opioid prescription drugs.

185. At all relevant times, the retail pharmacy customers were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct.

186. The sheer volume of prescription opioids flooding out of the doors of the Defendant Wholesale Distributors and into communities across the country, including Louisville Metro Area, shocks the conscience and required each Defendant Wholesale Distributor to take appropriate action, such as investigating and reporting the orders as suspicious. Given their place in the supply chain, the Defendant Wholesale Distributors are uniquely situated to identify suspicious transactions. However, determined to increase their revenues, each of the Defendant Wholesale Distributors willfully ignored obvious warning signs concerning suspicious orders. It would be virtually impossible for all of the orders to be legitimate, as there was no medical-need correlation justifying the skyrocketing orders for these addictive drugs.

187. For all times relevant to this Complaint, each Defendant exerted control over its Opioids Diversion Enterprise and participated in the operation and management of the affairs of the Opioids Diversion Enterprise, directly or indirectly, in the following ways:

a. Defendants obtained a license from the Kentucky Board of Pharmacy and the Kentucky Cabinet for Health and Family Services but, contrary to the requirements of Kentucky law, including federal laws incorporated into Kentucky law, Defendants failed to take necessary action to maintain effective controls against diversion of dangerously addictive prescription opioids, and in dereliction of non-delegable duties, sold opioid pills to their retail pharmacy customers notwithstanding that the increase and quantum of addictive drug orders raised serious red flags regarding the drugs' unlawful, non-medical use;

b. Defendants misrepresented their compliance with their legal obligations, making false assurances that their distribution complied with the law, including without limitation the requirements of a Kentucky distributor license, when, in truth, Defendants sold all the opioids they could, for profit, and in violation of their legal duties to guard against diversion of prescription opioids for illicit purposes;

c. Defendants refused to heed the DEA's warnings and continued to sell opioids and fill suspicious orders which were likely to be diverted;

d. Defendants refused to abide by the terms of DEA enforcement actions and settlements, continuing to sell opioids to fill suspicious orders;

e. Defendants did not monitor, detect, investigate, refuse to fill, and report suspicious orders to the DEA as required under the terms of their licenses and applicable law;

f. Defendants intentionally and/or unlawfully sold the opioids unlawfully, purely for profit and without regard to the opioid plague, notwithstanding Defendants' knowledge that substantial foreseeable harm would occur; and,

g. Defendants only succeeded in these opioid sales by using wire and mail to communicate with the retail pharmacies.

188. The retail pharmacies participated in each Defendant's Opioid Diversion Enterprise by employing mail and wire to send orders of opioids to Defendants and to buy opioids from Defendants. The retail pharmacies also participated in each Defendant's Opioid Diversion Enterprise by engaging with Defendants in violation of the Kentucky Controlled Substances Act and Kentucky law as described herein.

189. The scheme devised and implemented by each Defendant, as well as other members of each Defendant's Opioids Diversion Enterprise, amounted to a common course of conduct intended to profit from Opioid sales.

**C. Pattern of Racketeering Activity**

190. Each Defendant conducted and participated in the conduct of the affairs of each Defendant's Opioids Marketing Enterprise through a pattern of racketeering activity, which violates 18 U.S.C. § 1962(c).

191. Regardless of any licenses or registrations held by Defendants to distribute dangerous and harmful drugs, their conduct was neither "lawful" nor "authorized." Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

192. The pattern of racketeering activity alleged herein and each Defendant's Opioids Diversion Enterprise are separate and distinct from each other. Likewise, each Defendant is distinct from its respective Opioids Diversion Enterprise.

193. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

194. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, Defendants' misrepresentations to the public, the Kentucky Board of Pharmacy, the Kentucky Cabinet for Health and Family Services, and the DEA, depended on secrecy.

195. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Louisville Metro Area and its citizens. Each Defendant crafted its scheme to ensure its own profits remained high, without regard to the effect such behavior had on Louisville Metro Area and its citizens. In designing and implementing their respective schemes, at all times each Defendant was cognizant of the fact that those in the distribution chain and Kentucky Board of Pharmacy, the Kentucky Cabinet for Health and Family Services, and the DEA, *inter alia*, rely on the integrity of the wholesale distributors to maintain a closed system and to protect against the non-medical uses of these dangerously addictive opioid drugs.

196. Each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including the distribution of dangerous and harmful drugs to persons, including minors, in violation of the Kentucky Controlled Substances Act and related Kentucky laws, at retail pharmacies, hospitals, and other health care facilities throughout Louisville Metro Area.

197. Each Defendant's actions were in violation of Chapter 218A of the Kentucky Revised Statutes, and more specifically: § 218A.1404, which forbids unlawful distribution of controlled substances; § 218A.1404, which forbids the trafficking of controlled substances; and, KY. REV. STAT. ANN. § 506.040; KY. REV. STAT. ANN. § 218A.1402, which forbid criminal drug conspiracies; and KY. REV. STAT. ANN. § 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

198. Defendants violated Section 218A.1404 of the Kentucky Controlled Substances Act, which provides that, "No person shall dispense, prescribe, distribute, or administer any controlled substance except as authorized by law." KY. REV. STAT. ANN. § 218A.1404

199. Defendants violated § 218A.1404 of the Kentucky Controlled Substances Act, which provides that, "No person shall traffic in any controlled substance except as authorized by law". KY. REV. STAT. ANN. § 218A.1404(1). *See* KY. REV. STAT. ANN. §218A.010(55) ("'Traffic,' . . . means to . . . distribute, dispense, sell, transfer, or possess with intent to . . . distribute, dispense, or sell a controlled substance").

200. Defendants violated Kentucky Revised Statute Section 506.040 and Section 218A.1402 of the Kentucky Controlled Substances Act, which provides that a person commits criminal drug conspiracy when, with the intent that a crime be committed, it agrees with another to the commission of that offense. KY. REV. STAT. ANN. § 506.040; KY. REV. STAT. ANN. § 218A.1402.

201. Defendants also violated § 218A.1405 of the Kentucky Controlled Substances Act by "knowingly receiv[ing] any income derived directly or indirectly from trafficking in a controlled substance" and then using that income "establish or operate. . . [a] commercial enterprise." KY. REV. STAT. ANN. § 218A.1405.

202. Defendants do not qualify for the "authorized by law" exceptions to the Kentucky Controlled Substance Act violations because Defendants did not comply with the mandatory terms of the licenses issued to them by the Kentucky Board of Pharmacy, the Kentucky Cabinet for Health and Family Services, or with federal requirements incorporated by reference, as further detailed in this Complaint.

203. Defendants' violations of the Kentucky Controlled Substances Act qualify as felonies carrying a prison term in excess of one year, and therefore the violations constitute racketeering activity under 18 U.S.C. § 1961(1)(A).

204. In addition, each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including thousands of separate instances of use of the United States Mail or interstate wire facilities in furtherance of each Defendant's unlawful Opioids Diversion Enterprise. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity. Each Defendant specifically intended to obtain money by means of false pretenses, representations, and promises, and used the mail and interstate wires for the purpose of executing this scheme; specifically, each Defendant communicated with its respective retail pharmacy customers via wire and used the mail to receive orders and sell drugs unlawfully. Any violation of the mail or wire fraud statutes is defined as "racketeering activity." 18 U.S.C. § 1961(1)(B).

**D. Damages**

205. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused, and/or have been a substantial factor causing, the Plaintiff to be injured in its business or property because Plaintiff has paid for costs associated with the opioid epidemic, as described in this Complaint.

206. The Plaintiff's injuries proximately caused by Defendants' racketeering activities. But for Defendants' conduct, the Plaintiff would not have paid *inter alia* the health services and law enforcement services expenditures required by the plague of drug-addicted residents.

207. The Plaintiff's injuries were directly caused by Defendants' racketeering activities.

208. The Plaintiff was most directly harmed, and there is no other Plaintiff better situated to seek a remedy for the economic harms at issue here.

**COUNT III**
**NEGLIGENCE**
**KENTUCKY COMMON LAW**

209. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further allege as follows.

210. Each Defendant had an obligation to exercise due care in distributing highly dangerous opioid drugs in Louisville Metro Area.

211. To recover on a common law negligence claim in Kentucky, there must be a duty on the defendant's part, a breach of that duty, and consequent injury.

212. Kentucky law has adopted a "universal duty of care" which requires every person to exercise ordinary care in his activities to prevent foreseeable injury. *See T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526 (Ky. 2006). If a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury. Each Defendant owed a duty to the Plaintiff, and to the public in Louisville Metro Area, because the injury was foreseeable, and in fact foreseen, by the Defendants.

213. Each Defendant owed a duty to the Plaintiff because the injury was likely. Each Defendant was required to guard against the injury as a requirement for the licenses each Defendant maintains, and the burden of guarding against the injury was voluntarily assumed and

not unduly onerous. The burden of guarding against the injury is properly placed upon each Defendant, and indeed, federal and state licensing and registration requirements required that each Defendant guard against the diversion of dangerously addictive opioids for illicit purposes.

214. Reasonably prudent wholesale drug distributors would have anticipated that the scourge of opioid addiction would wreak havoc on communities. As explained above, the system whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies exists ***for the purpose*** of controlling dangerous substances such as opioids. Defendants were repeatedly warned by law enforcement. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

215. As described above in language expressly incorporated herein, Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by filling highly suspicious orders time and time again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

216. In addition, Defendants' violations of public safety laws are prima facie evidence of negligence. Each Defendant had a duty under, *inter alia,* these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

217. As described above in language expressly incorporated herein, Defendants' breach of duty caused, bears a causal connection with, was and is a substantial factor contributing to, and/or proximately resulted in, harm and damages alleged herein.

218. As described above in language expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes and regulations requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

219. As described above in language expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and/or proximately resulted in, harm and damages alleged herein.

220. It was foreseeable that the breach of duty described herein would result in the damages alleged herein.

221. Defendants acted with actual malice, willfully, and with such gross negligence as to indicate a wanton disregard of the rights of others. Punitive damages are necessary to deter similar conduct in the future.

**COUNT IV**
**NEGLIGENCE PER SE**
**KENTUCKY REVISED STATUTES § 446.070**

222. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further allege as follows.

223. The Kentucky General Assembly has declared that "[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public

safety and public health." KY. REV. STAT. ANN. § 218A.005(1). Further, the Kentucky has declared that "effective control and regulation" of all "persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth" is necessary in order to "promote, preserve, and protect public health, safety, and welfare." KY. REV. STAT. ANN. § 315.005. Kentucky Board of Pharmacy regulations state that "[a] wholesale distributor shall not . . . operate in a manner that endangers the public health." 201 KY. ADMIN. REG. 2:105 §7.

224. Accordingly, Kentucky's minimum requirements for wholesale drug distribution mandate that "all sales and distributions shall be in accordance with . . . the federal controlled substances laws . . . ." KY. REV. STAT. ANN. § 218A.170. As wholesale drug distributors, each Defendant was required under Kentucky law to first be licensed by the Kentucky Cabinet for Health and Family Services. KY. REV. STAT. ANN. § 218A.150. To receive and maintain this license, each of the Defendant Wholesale Distributors assumed a duty to comply with "all applicable federal and state laws and regulations relating to controlled substances." KY. REV. STAT. ANN. § 218A.160(1)(a). Kentucky Board of Pharmacy licensure requirements mandate that a wholesale distributor "continue[] to demonstrate acceptable operational procedures, including . . . compl[iance] with all DEA regulations." 201 KY. ADMIN. REG. 2:105 §2(4)(d).

225. The federal laws and requirements which Kentucky incorporates into its own laws require Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs. *See* Kentucky laws incorporating federal requirements (KY. REV. STAT. ANN. § 218A.170(4); KY. REV. STAT. ANN. § 218A.160(1)(a); 902 KY. ADMIN. REGS. 55:010(h)(2)(b); 201 KY. ADMIN. REG. 2:105 §2(4)(d)).

226. The federal mandates incorporated into Kentucky law require that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). These federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

227. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). Regardless, all flagged orders must be reported. *Id.*

228. Each Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act, as incorporated into Kentucky law. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each of the Defendant Wholesale Distributors is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

229. Each Defendant's actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, and also including § 218A.1404, which forbids unlawful distribution of controlled substances; § 218A.1404, which forbids the trafficking of controlled

substances; and, KY. REV. STAT. ANN. §§ 506.040 and 218A.1402, which forbid criminal drug conspiracies; and KY. REV. STAT. ANN. § 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

230. Kentucky Revised Statutes § 446.070, "Penalty no bar to civil recovery," provides for the right to recover damages sustained by a violation of any Kentucky statute or public safety regulation, stating: "A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation." "Person" is broadly construed to include "bodies-politic and corporate, societies, communities, the public generally, individuals, partnerships, joint stock companies, and limited liability companies." KY. REV. STAT. ANN. § 446.010(33).

231. Section 446.070 creates a private right of action in a person damaged by another person's violation of any statute even where the statute is penal in nature and provides no civil remedy, if the person damaged is within the class of persons the statute intended to be protected. Section 446.070 also extends to Kentucky administrative regulations where adopted pursuant to an enabling statute and where such regulations concern public safety.

232. Louisville Metro is within the class of persons intended to be protected by the public safety statutes and regulations concerning wholesale distribution of controlled substances.

233. Defendants' violations of these public safety laws are prima facie evidence of negligence and a violation of Section 446.070. Each Defendant had a duty under, *inter alia,* these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

234. As described above in language expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes and regulations requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

235. As described above in language expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and/or proximately resulted in, harm and damages to Plaintiff.

236. The injuries and damages sustained are those which the Kentucky statutes and public safety regulations were designed to prevent.

237. Defendants' violations of the Kentucky statutes and public safety regulations cited herein were and are a substantial factor in the injuries and damages sustained.

238. It was foreseeable that Defendants' breach of statutory and regulatory duties described herein would result in the damages sustained.

## V. CONCLUSION

239. Defendant Wholesale Distributors had a duty to abide by safety laws and maintain effective controls against diversion of controlled substances under both Kentucky and federal law, including a duty to monitor, detect, report, and refuse to fill suspicious orders of prescription opioids. Plaintiffs alleges that the Defendant Wholesale Distributors unlawfully, negligently, and intentionally breached their duties under federal and Kentucky law, and that such breaches are a proximate cause of the opioid epidemic plaguing Louisville Metro. Defendants actions were and are a substantial contributing factor to the harms alleged herein. The unlawful, intentional, and negligent conduct by the Defendant Wholesale Distributors has

created a hazard to public health and safety in Louisville Metro Area and constitutes a public nuisance under Kentucky law.

## VI. AD DAMNUM

**WHEREFORE**, Plaintiff, Louisville/Jefferson County Metro Government, hereby respectfully request trial by jury and that this Court adjudge and decree that Defendants are liable for creating a public nuisance, enter judgment for the Plaintiff and against Defendants, award the relief requested in each *prayer for relief* above, and:

1. Enter Judgment in favor of the Plaintiff in a final order against each of the Defendants;
2. Enjoin the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them, from engaging in unlawful sales of prescription opioid pills and ordering temporary, preliminary or permanent injunction;
3. Allocate monetary damages attributable to each Defendant for each Count pled above;
4. Order that Defendants compensate the Plaintiff for its past and future damages and costs to abate the ongoing public nuisance caused by the opioid epidemic;
5. Impose an award of actual and triple the actual damages the Plaintiff sustained as a result of each Defendant's violation of the Racketeer Influenced and Corrupt Organizations Act, and any allowable civil penalty;
6. Order that each Defendant pay restitution;
7. Order that each Defendant disgorge profits;
8. Order that each Defendant is liable for civil penalties under Kentucky law;

9. Allocate monetary damages attributable to each Defendant to compensate the Plaintiff for the expenses and costs that it bears as a result of the public nuisance, including without limitation (A) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments/services for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs associated with law enforcement and public safety relating to the opioid epidemic, including without limitation first responders and ambulance services; and (E) any other expenses or damages caused by the Defendants' diversion of opioids;
10. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance and otherwise abate the public nuisance;
11. Award judgment against the Defendants requiring Defendants to pay punitive and exemplary damages;
12. Grant the Plaintiff:
    a. Court costs, including reasonable attorney fees;
    b. Pre-judgment and post-judgment interest, and,
    c. All other relief as provided by law and/or as the Court deems appropriate and just.

Plaintiff asserts claims herein in excess of the minimum jurisdictional requirements of this Court.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Date: August 21, 2017

/s/ *Michael J. O'Connell*

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